Minutes of Meeting

Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

January 26, 2005
1:00 p.m.

Attendees: Garry Magouirk, Chair; Richard Freeman, Jackie Feldman, A.Z. Holloway, Mary McIntyre, Ben Main, Jimmie Clark, Sheri Boston, Dane Yarbrough, Louise Jones, Janelle Sheen

Absent: David Herrick

(1) OPENING REMARKS
Garry Magouirk called the meeting to order at 1:09 p.m. and asked that all cell phones and pagers be placed in the off position.

(2) Chairman Magouirk asked if there were corrections to the minutes from the October P&T meeting. Dr. Feldman asked for clarification on page 26 of the minutes, under section T., if the statement regarding tiotropium meant the amended recommendation was accepted. Louise Jones and Dr. McIntyre both commented that the amended recommendation was accepted. Dr. Feldman motioned to approve the minutes and Dr. Freeman seconded the motion.

(3) Louise Jones gave the pharmacy program update:

Ms. Jones introduced several new staff members who are working in the Pharmacy Services Division. Bakeba Thomas will be administratively working with the Pharmacy and Therapeutics Committee and Preferred Drug List (PDL). Tiffany Minnifield is working with the Health Information Design (HID) contract and the DUR Board function. Stephanie Frawley is a certified pharmacy technician working with Pharmacy Services through the HID contract. Finally, Anita Jones, who has been with the agency for a while now, is working with the federal drug rebate program.

Through the initiatives of the Pharmacy and Therapeutics Committee (and other initiatives such as PDL, brand limit, therapeutic duplication, and neuroscience CNS project for mental health drugs), the state has achieved a savings of $119 million per year. Since some of the programs overlap, it is difficult to identify specific savings for individual programs. The agency is monitoring the savings and continues to make sure the initiatives are not leading to increases in dollars spent for other programs, such as in emergency room visits, hospitalizations, and doctor visits. So far, with monthly monitoring, the agency has not seen increases in other program dollars as a result of any of the initiatives put in place.

Dr. Feldman asked if the committee could receive the absolute numbers for other program areas (hospitalizations, emergency room visits, etc.). Ms. Jones acknowledged that those numbers would be available to the committee and the agency would provide the current numbers.

The anti-infective review will be completed at this meeting, and are the second part of the anti-infective review. Recommendations from the October and January meetings will be applied to the PDL as of March 1, 2005. A notice has been drafted to all providers pertaining to the PDL updates.

For the first time, the agency has elected to place generic medication on prior authorization. Until now, all generic medications have been available without prior authorization. Generic OxyContin will be placed on prior authorization, along with the rest of the sustained-release oral opioids. This is a result of concern over utilization of these drugs. This will take effect March 1, 2005.

The Agency has implemented the brand limit switch-over program. The four brand limit went into effect July 1, 2004. The switch-over program went into effect November 22, 2004 to allow providers to switch patients from one brand to another within the same class, if the physician documents medical necessity.

Electronic prior authorization has been implemented December 1, 2004 for the non-steroidal anti-inflammatory drugs (NSAIDs), including COX-II drugs, second-generation anti-histamines, and sustained-release oral opioids. Other PDL classes will be phased into the electronic prior authorization program over the next few months. Manual prior authorization demand should be reduced by 40%. Additionally, maximum quantity limits will be placed on all PDL drugs. The maximum units are established based on FDA dosing recommendations and will be made available to providers on the Medicaid website.

Blue Cross Blue Shield's electronic claims program, through InfoSolutions, went live December 1, 2004. This program makes patient claims data available to physicians through a hand-held palm device. The state has provided pharmacy claims data to be used in the program, so that providers will have access to patient pharmacy information in their office. The Agency is still working with Blue Cross Blue Shield to transfer medical claims data, that will be available in the future. Various means to distribute the software to physicians have been discussed. Currently, Ms. Jones explained it is believed the software is being provided at no cost to providers; however, providers must supply the actual device. The Agency can let providers know who to contact at Blue Cross for more information on obtaining the software.

Louise gave an update on the invitation to bid (ITB). The ACS-Heritage contract for PDL support is coming to an end January 31, 2005. The current meeting is ACS-Heritage's last meeting under this contract. The Agency is evaluating how they can more efficiently run the PDL program. In the past, the PDL and rebating has all been done in-house. The clinical reviews have been the only part of the PDL process that has been outsourced. Many states contract these services out to companies who are able to do all services related to maintaining a PDL, including rebating, reviews, administrative tasks, and the Pharmacy and Therapeutics Committee. The Agency is in the process of making sure the ITB is complete and comprehensive in listing the detail involved with the PDL process and needs of the contract, to better maximize the Agency's staffing and time. The Agency held a round-table discussion with several vendors this past week, to get ideas on what other states are doing that Alabama might benefit from, both financially and administratively. These ideas will be included in a comprehensive ITB, to be issued within the next one to two months. With this in mind, the date of the next Pharmacy and Therapeutics Committee meeting has not been set. It is possible the Committee will pick back up with a rapid schedule as the new contractor comes on board. Many drug classes are in need of re-review, and other classes may come up that have not been reviewed. The Agency is open to any cost-containment ideas.

Dr. Feldman brought up the Medicare prescription drug benefit program. Louise Jones explained that there is a misconception that this program will take a financial burden off the Medicaid program. She explained that Medicaid pays a per member rate to CMS based on cost per member at a time when there were not a lot of savings initiatives in place. Because of this, the base year for comparison is 2003, when many pharmacy initiatives were not in place, or were just being implemented. The agency will be paying a disclosed rate which does not reflect the pharmacy savings achieved from these initiatives. If anything, Medicaid will financially be hurt. Louise explained that an update could be given at the next meeting.

(4) Louise Jones introduced Dr. Garry Magouirk as the new Pharmacy and Therapeutics Committee Chair. He will lead the committee over the next year.

(5) PHARMACOTHERAPY REVIEWS (Refer to the web for full text reviews):

Dr. Magouirk explained the process for the manufacturer presentations and introduced a lighted signal system to inform each presenter when his/her time has expired.

Ms. Sheen began discussion by explaining there were nine scheduled pharmacotherapy classes for review, some with single entity and combination reviews. Additionally, there were three new drug reviews.

The pharmacotherapy reviews began at approximately 1:28 p.m. Five-minute verbal presentations were made on behalf of some pharmaceutical manufacturers. The drugs with manufacturer representatives who spoke on their behalf are listed below prior to each therapy class description. There were a total of eight manufacturer presentations at the meeting.
Section I. Anti-infectives

Macrolides, Single Entity Agents (AHFS Class 081212)
Manufacturer comments on behalf of these products:
Zithromax, Z-Pak (azithromycin)

Ms. Sheen began the Anti-infective reviews with the single entity macrolides. She explained there are four drugs in this class and asked the members of the committee to make a correction to the clarithromycin dosing on page 12. Erythromycin is the only available generic. The agents are active against gram-positive cocci (staphylococci and streptococci). They are active to a lesser extent for gram-negative organisms. Gram-negative organisms covered include Bordetella pertussis, Campylobacter, Chlamydia, Helicobacter, and Legionella species. Janelle commented that azithromycin and clarithromycin have oral bioavailabilities greater than erythromycin and possess greater intrinsic activity against Haemophilus influenzae. Both of these agents are associated with fewer adverse events compared with erythromycin (gastrointestinal), and azithromycin has less potential for drug interactions. In looking at indications, clarithromycin has demonstrated efficacy for eradication of *H. pylori* and is approved for acute maxillary sinusitis. Azithromycin is approved for gonococcal sexually transmitted diseases, as well as Chlamydia and Chancroid. Dirithromycin lacks *H. influenzae* activity, does not have a liquid formulation, and the safety and efficacy has not been established in children less than 12 years of age. In the treatment of mycobacterium avium complex (MAC), clarithromycin is approved for treatment in children, while azithromycin is only approved for treatment and prophylaxis of MAC in adults. Treatment guidelines for MAC recommend use of both drugs, however, azithromycin is the treatment of choice for prophylaxis of MAC in pregnant women. Biaxin XL has 3 indications: maxillary sinusitis, acute exacerbations of chronic bronchitis, and community-acquired pneumonia.

The clinical literature says that clarithromycin and azithromycin are comparable in efficacy and safety for acute otitis media, pharyngitis, community-acquired pneumonia, and MAC. Azithromycin, erythromycin estolate, and amoxicillin/clavulanate are equivalent in efficacy for community-acquired pneumonia.

In looking at dose simplification, a study of dirithromycin once daily versus clarithromycin twice-daily showed that four dirithromycin patients were non-compliant and twelve clarithromycin patients were non-compliant, however, the difference was not significant. In another study, of clarithromycin versus erythromycin, the mean percentage of drug taken was 98.5% for clarithromycin and 88.6% for erythromycin. This study did not further report any impact this had on clinical outcomes.

Pertaining to adverse events, a tolerability study of azithromycin and other antibiotics showed that adverse events with azithromycin were significantly lower, but discontinuation rates between azithromycin and other comparable anti-infectives were similar. Yet another study of clarithromycin and erythromycin showed higher adverse event rated with erythromycin, but only three erythromycin patients and one clarithromycin patient discontinued due to adverse events.

Janelle concluded that all brand products within the single entity macrolide class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand single entity macrolide was recommended for preferred status.

Dr. Feldman commented that clinical study data does not always represent actual practice experiences. She cited several bullet points from studies in the single entity macrolide review on the incidence of adverse events, stating that she feels the clinical study data and real world data is different. She commented that drop-out rates of patients discontinuing medication is very important and can mean a significant difference in treatment. She asked other members of the committee to speak to their experiences with these drugs and adverse events. Dr. Freeman added to the discussion that in his practice he looks to prescribe drugs that will "get the job done", comparing this scenario to different brands of gasoline. He also commented that adverse event rates are an important factor in this class, as well as the number of patients he sees with mycobacterial infections that cannot be cured with erythromycin. Janelle asked the committee if they would feel more comfortable with the recommendation of the Agency working with the manufacturers so that at least one brand drug in the class is placed in preferred status. Sheri Boston commented on increased drug-interactions with the drugs in the class besides azithromycin, and she feels this is significant and should be considered. Dr. Feldman motioned to amend the recommendation presented, to include that azithromycin be placed in preferred drug status. Dr. Clark seconded the motion.

Garry Magouirk asked the Board to mark their ballots.

Macrolides, Combination Agents (AHFS Class 081212)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the one combination macrolide anti-infective, erythromycin ethylsuccinate and sulfisoxazole. The drug is available in an oral suspension under the brand name Pediazole. The indication for this drug is acute otitis media in children = 2 years, caused by susceptible strains of Haemophilus influenzae. Both drugs within the combination product offer some activity against *S. pneumoniae,* but resistance is increasing.
The literature and evidence pool suggests that neither erythromycin/sulfisoxazole nor cefaclor should replace amoxicillin as a first-line treatment for otitis media. Additional studies document a preference for amoxicillin as the preferred antibiotic for new episodes of acute otitis media. One study compared erythromycin/sulfisoxazole with amoxicillin plus clavulanate and showed no statistically significant difference in efficacy. Additionally, the American Academy of Pediatrics treatment guidelines for otitis media suggest observation with symptomatic treatment instead of antibiotic therapy, but still suggest the aminopenicillins (amoxicillin) remain first-line agents for most children with otitis media. The combination of erythromycin/sulfisoxazole is recommended as alternative therapy. Generic options are available for the recommended first-line agents, as well as other recommended therapies. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand combination macrolide antibiotic was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the Board to mark their ballots.

Quinolones (AHFS Class 081218)
Manufacturer comments on behalf of these products:
Levaquin (levofloxacin)
Avelox (moxifloxacin)
Cipro XR (ciprofloxacin extended-release)

Janelle Sheen discussed that there are ten different quinolone antibiotics, with two recent generic drugs available (ciprofloxacin and ofloxacin). She mentioned a new quinolone approved this past September, gemifloxacin that will be reviewed at a future meeting. As far as indications of the quinolones, ciprofloxacin remains the gold standard treatment for *P. aeruginosa*. It has the most expansive indications compared to other quinolones, although it lacks indications for sexually transmitted diseases. Treatment guidelines from the Centers for Disease control do recommend use of ciprofloxacin for certain sexually transmitted diseases. Ciprofloxacin is the quinolone that has been studied most extensively in children, although in general, the quinolones should not be used in children less than 18 years of age. Cipro XR is indicated for urinary tract infection.

Looking at anaerobic coverage, moxifloxacin and gatifloxacin have the greatest coverage, while levofloxacin, gatifloxacin, and moxifloxacin all provide adequate respiratory coverage and are options for community acquired pneumonia due to enhanced coverage against gram-positives.

Most drug interactions and adverse events are of a class effect with the quinolones. Limited comparative data is available on the efficacy of these agents. Of the fourteen studies presented in the review, all quinolones compared were found to be comparable in efficacy.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand quinolone was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the Board to mark their ballots.

Sulfonamides, Single Entity Agents (AHFS Class 081220)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen presented information for the three single entity sulfonamide agents: sulfadiazine, sulfasalazine, and sulfisoxazole. A generic formulation is available for each of the agents in this class. Exceptions include Azulfidine EN and Gantrisin Pediatric. The Gantrisin Pediatric suspension is comparable in efficacy with the generic tablet formulation, and for sulfasalazine, it is an option for patients with rheumatoid arthritis, but may not be a typical first-line agent for either condition. Sulfasalazine is indicated for ulcerative colitis and rheumatoid arthritis. Sulfadiazine and sulfisoxazole are similarly indicated for urinary tract infections, certain sexually transmitted diseases, conjunctivitis, resistant malaria, meningitis, nocardiosis, otitis media, and rheumatic fever. Looking at the clinical evidence, primarily presented for sulfasalazine, in the treatment of ulcerative colitis, a study of sulfasalazine versus azathioprine produced comparable relapse rates. In the treatment of rheumatoid arthritis, aggressive therapy with a combination of three disease-modifying anti-rheumatic agents compared with sulfasalazine monotherapy showed favorable response early on with the combination treatment group, however at five years, the difference in remission of disease was not significant between the groups. Additionally, a study of rheumatoid arthritis in patients inadequately responding to leflunomide showed benefit with the addition of sulfasalazine therapy. Therefore, all branded products within the class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over alternatives in general use. No brand single entity sulfonamide was recommended for preferred status.

Dr. Feldman asked for clarification on the generic availability of the agents in this class and Janelle Sheen stated that each drug ingredient has at least one generic formulation available; however, the Azulfidine EN tablets are brand only.

Garry Magouirk asked the Board to mark their ballots.

Sulfonamides, Combination Agents (AHFS Class 081220)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen began discussion of the combination sulfonamide agents, trimethoprim/sulfamethoxazole and the triple sulfa vaginal products. Janelle discussed the trimethoprim/sulfamethoxazole agent first, explaining that all dosage formulations are available in a generic formulation. The drug is indicated for and is effective against urinary tract infections, shigellosis, pneumocystis carinii pneumonia, otitis media, acute exacerbations of chronic bronchitis, and travelers diarrhea. It remains the first-line treatment for acute, uncomplicated urinary tract infections.

Janelle spoke secondly about the vaginal sulfonamide agents. She explained that their availability is limited, and the Food and Drug Administration (FDA) has recommended, based on clinical literature, that no adequate evidence is available to support the effectiveness of the agents for vulvovaginitis or for relief of the symptoms associated with this condition. USP medical experts are in agreement with the FDA's recommendation, and denote the vaginal sulfonamides are not effective for any vaginal indication. Therefore, all brand products within the combination sulfonamide class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over the alternatives in general use. The availability and effectiveness of the vaginal sulfonamide agents does not support benefits of their use. No brand combination sulfonamide was recommended for preferred status. Additionally, the vaginal sulfonamide agents should not be placed in preferred status regardless of cost. Dr. Holloway commented that if the vaginal sulfonamides aren't effective, then why is it that Medicaid is covering them? Louise Jones answered that the state is required by legislation to cover the products. Dr. Magouirk added that the vaginal agents simply aren't used much anymore because they are not effective.

Garry Magouirk asked the Board to mark their ballots.

Miscellaneous Antibacterials, Single Entity Agents (AHFS Class 081228)
<u>Manufacturer comments on behalf of these products:</u>
Cubicin (daptomycin)

Janelle Sheen preceeded the content of this review noting that the drugs in this review were used for varying indications, making it challenging to directly compare the agents in the class.

The single entity miscellaneous antibacterials include both intravenous and oral agents, some of which are available intravenously as well. Oral clindamycin is available as a generic. Use of the agents in this class is primarily for hospitalized patients or for limited use in specific infections. Some (lincomycin and polymyxin B) are not used as first-line agents.

Oral vancomycin for pseudomembranous colitis is used with metronidazole is not effective, in serious disease, allergic patients, or in cases of resistance. In general, use of these anti-infectives is reserved for more serious infections. Taking a high level overview, indications of the agents in this class include respiratory tract infections including pneumonia, bone and joint infections, skin and skin structure infections, and resistant infections (MRSA). Most oral use is likely for respiratory tract infections, soft tissue infections, bone and joint infections, colitis, and resistant infections. There may be some clinical advantage to the drugs in this class in special circumstances, but there is not a role for these agents in general use. Therefore, all brand products within the class reviewed are comparable to each other and to the generics in the class and offer no significant clinical advantage over other alternatives in general use. No brand single entity miscellaneous antibacterial was recommended for preferred status.
No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the Board to mark their ballots.

Miscellaneous Antibacterials, Combination Agents (AHFS Class 081228)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the two combination agents in this class: bismuth subsalicylate/metronidazole/tetracycline (Helidac) and dalfopristin/quinupristin (Synercid). The bismuth combination product is packaged together, it is not a single formulated tablet that encompasses all three drug ingredients. The Helidac combination is not available generically, however, all of the drug ingredients within the package are available individually as generic drugs. This combination is indicated for the treatment of *H. pylori*. An H-2 antagonist must be added to the bismuth combination product for appropriate *H. pylori* eradication therapy. A meta-analysis has shown that triple and quadruple therapies are roughly equivalent in effectiveness, compliance, and side-effects for first-line treatment of *H. pylori* infection. With dalfopristin/quinupristin, the other combination drug in the class, use is limited to hospitalization therapy. The drug is indicated for serious or life-threatening infections associated with vancomycin-resistant enterococcus (VRE) bacteremia, and also for complicated skin and skin structure infections caused by *S. aureus* or *S. pyogenes*. Dalfopristin/quinupristin is a major inhibitor of the cytochrome P450 enzyme system. Clinical studies indicated this combination is comparable to linezolid for VRE infections and is similar to vancomycin for gram positive nosocomial pneumonia.

Due to the indications and use of this drug, there is not a role for it as an anti-infective agent in general use. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products within the class and offer no significant clinical advantage over other alternatives in general use. No brand combination miscellaneous antibacterial was recommended for preferred status.

Dr. Clark commented on current use of the Helidac and the four brand limit. Dr. McIntyre stated that both Helidac and Prevpac are currently on prior authorization and there haven't been problems with the criteria or process for these agents. She further clarified that the generics within the Helidac combination are first-line, and patients must meet criteria and have failed use with the generics, in order to get Helidac. Dr. McIntyre described that when the generics are used, they do not count against the brand limit.

Garry Magouirk asked the Board to mark their ballots.

Antimycobacterials, Single Entity Agents (AHFS Class 081600, 081604, 081692)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen presented clinical information on the antimycobacterial single entity agents for the treatment of leprosy (Hansen's disease) and tuberculosis. Tuberculosis has emerged as the single leading cause of death from any single infectious agent. Treatment involves multiple drugs due to resistance, and the need for both bactericidal (isoniazid and rifampin) and sterilizing (rifampin and pyrazinamide) activity. The CDC recommends the following first-line treatments: isoniazid, rifampin, rifabutin, rifapentine, pyrazinamide, and ethambutol. Most regimens prefer rifampin, with rifabutin and rifapentine as alternative therapies. Second-line agents include cycloserine and ethionamide. The Centers for Disease Control (CDC) recommended treatment regimens include three to four combinations of drugs for an initial phase of therapy, followed by a continuation phase, for a total duration of 26-39 weeks. Generic formulations are available for all first-line agents except for rifabutin and rifapentine. Drug-induced hepatitis and liver problems are the most common severe adverse event with these agents.

In the treatment of leprosy, the drugs used are dapsone and clofazimine. In 2002, there were 96 cases of the disease in the United States. Treatment of leprosy is not within the scope of general use, but these agents should be made available when needed for their indicated uses, through prior authorization. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in this class and offer no significant clinical advantage over other alternatives in general use. No brand single entity antimycobacterial was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the board to mark their ballots.

Antimycobacterials, Combination Agents (AHFS Class 081600, 081604, 081692)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen presented the two combination drugs in this class: isoniazid/rifampin (Rifamate) and isoniazid/rifampin/pyrazinamide (Rifater). No generic formulations are available for these combination products. Much of the clinical data on the treatment of tuberculosis that was discussed in the previous review is just as pertinent to this review as well. Both combination agents are indicated for the treatment of tuberculosis. Only 15% to 18% of rifampin is sold in a fixed-dose combination products, largely because the brand names of these drugs are so similar and they have resulted in prescribing and dispensing mistakes. Additionally, the clinical evidence available for the fixed-dose combination products does not suggest a clinical benefit versus use of the separate entity agents. Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant advantage over other alternatives in general use. No brand combination antimycobacterial agent was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the board to mark their ballots and called for a ten minute recess. The break was instituted at 2:35 p.m. and the meeting resumed at 2:48 p.m.

Anti-influenza Agents (AHFS Class 081804, 081828)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen began discussion in this class with an overview of the ion channel inhibitors (amantadine and rimantadine) and the neuraminidase inhibitors (oseltamivir and zanamivir). She explained that amantadine is classified as both a central nervous system agent and an anti-infective. Both amantadine and rimantadine are available as generic formulations. The CDC issued antiviral use guidelines this past fall, in light of flu vaccines being in short supply. Highlights from the guidelines included use of amantadine or rimantadine for chemoprophylaxis, and use of oseltamivir or zanamivir for the treatment of influenza. Also, high risk individuals should be given priority for antiviral medications as well as persons who live or work in institutions caring for people at high risk. In children, rimantadine is approved in those = 1 year for prophylaxis, other options for treatment include: amantadine and oseltamivir (= 1), and zanamivir (= 7). The CDC also warns that antiviral medication use is highly dependent on local supply of medication.

As for indications, amantadine and rimantadine are approved for influenza type A virus. Rimantadine lacks an indication for treatment in children, while amantadine is indicated for the treatment of parkinsonism and drug-induced extrapyramidal symptoms. Oseltamivir and zanamivir are approved for influenza type A and B virus. Zanamivir is not indicated for prophylaxis and is not recommended for patients with underlying airway disease.

Janelle clarified the differences between influenza type A and B. Type A influenza is the primary isolated virus. This virus can adapt and change rapidly, and often results in a population without protective antibodies. Type A virus is responsible for pandemics and large population based outbreaks. Since the 1968 influenza pandemic, the greatest numbers of influenza associated hospitalizations have occurred during epidemics caused by type A viruses. Influenza type B is typically responsible for outbreaks in more confined areas like schools and the military. This virus is more stable and less able to adapt and change.

Looking at adverse events, rimantadine induces fewer central nervous system adverse events compared to amantadine, and both amantadine and rimantadine should be used with caution in patients with a seizure history. The anti-influenza agents are all oral except for zanamivir, which is a dry powder inhaled therapy. The frequency of dosing is typically BID for treatment and QD or BID for prophylaxis. Duration of therapy is treatment and drug specific and ranges from 3-7 days, and up to 6 weeks for prophylaxis. With regards to efficacy, according to the CDC, all four antiviral medications are similarly effective in reducing the duration of illness by one to two days. No direct comparative studies on the efficacy and safety of ion channel inhibitors or neuraminidase inhibitors are available. Therefore, based on the CDC recommendations and the available clinical literature, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. The Alabama Medicaid Agency may consider evaluation of oseltamivir and zanamivir and making these drugs available through medical justification through prior authorization, to ensure use primarily for the treatment of influenza, as indicated by the CDC recommendations. No brand anti-influenza agent is recommended for preferred status.

Dr. Feldman commented on the availability of the agents, if needed on weekends. Louise Jones added that HID does have weekend hours on Saturday to issue prior authorizations and additionally, all pharmacies have a generic PA number they can issue for up to a 72 hour supply of medication. Dr. McIntyre added that patients would need to meet criteria to get the branded agents, but that the Agency had previously discussed the handling of an influenza B outbreak through the prior authorization process and/or without prior approval, to make sure the drugs are available. Dr. Clark asked about the criteria for the branded drugs and Dr. McIntyre clarified that the criteria would follow closely with failure of other agents or for indications of the drugs (influenza type B).

Dr. Holloway asked if pharmacists were aware of the generic PA number and Louise Jones answered that the number has been provided to pharmacies and this is an ongoing education issue for the Agency. Dr. McIntyre commented that physicians who need these drugs on a weekend can also remind the pharmacy of the availability of the generic PA number for a 72 hour fill of medication. Louise Jones reminded the committee that the generic PA number for pharmacies is for urgent use situations only.

Garry Magouirk asked the board to mark their ballots.

Interferons (AHFS Class 081820)
Manufacturer comments on behalf of these products:
Pegasys (peginterferon alfa-2a)
Peg-Intron (peginterferon alfa-2b)

Janelle Sheen described this class of six injectable interferons. They are used for a variety of diseases including Kaposi's sarcoma, hepatitis B and C, and certain types of cancers. No generic formulations are available. Looking at indications for the interferons, five agents are indicated for the treatment of hepatitis C, however, treatment is based on genotype of the virus. Interferon therapy should be given in combination with ribavirin for hepatitis C. Interferon alfa-2a is also indicated for hairy cell leukemia, AIDS related Kaposi's sarcoma, and chronic myelogenous leukemia. Interferon alfa-2b is indicated for hairy cell leukemia, AIDS related Kaposi's sarcoma, condylomata acuminate, Non-Hodgkins follicular lymphoma, and malignant melanoma. Interferon alfa-N3 has a single indication for condylomata acuminate in patients = 18 years of age. All interferons within the class (with the exception of Alferon-N) have black box warnings for the potential to cause or aggravate fatal life threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. When used in combination with ribavirin, an additional black box warning is relevant as ribavirin can cause birth defects and/or death of the fetus. Other common adverse events include flu-like symptoms, which are reported in 30% of patients after the first treatment session. Thinning of hair is also common.

Dosing varies by indication and drug. Administration is typically two (Alferon-N for condylomata acuminate) to three times (chronic hepatitis) weekly (can be once daily for induction dosing) with the exception of the pegylated interferons, which are administered once weekly. Studies do not indicate improved efficacy with less frequent administration.

The efficacy literature suggests interferon therapy plus ribavirin for hepatitis C is more effective than interferon therapy alone. When comparing interferons for hepatitis C, the pegylated interferons offer significant clinical advantage when used for hepatitis C, based on virologic response rates. The interferons for condylomata acuminate, hairy cell leukemia, and Kaposi's sarcoma have shown promise for these conditions, although the literature for condylomata acuminate does suggest that other therapies should be tried prior to initiation of interferon for this condition.

Therefore, the pegylated interferons offer significant clinical advantage when used for hepatitis C. However, at this time, there is not a role for the interferon agents in general use. Due to narrow indications with limited use, the interferons should be available for special needs/circumstances that require medical justification through the prior authorization process. After clinical circumstances are explored, proper medical justification will provide access to these agents. The remaining agents in the class are comparable to each other and to the generics and OTC products and offer no significant clinical advantage over other alternatives in general use. No brand interferon was recommended for preferred status.

Dr. Holloway commented that the pegylated interferons are recommended by the National Institutes of Health (NIH) in the treatment of hepatitis C. Janelle Sheen responded that the conclusion made fully agreed that the pegylated interferons should be recommended in the treatment of hepatitis C, but that the agents were not pertinent in general use. Dr. McIntyre added that the hepatitis C indication is specific and can be addressed through medical justification, and when the interferons are given in a prescriber's office and charged via J code, they are not subject to compliance with the PDL. The PDL only applies when an actual prescription is written for an interferon to be filled at the pharmacy. Discussion further centered around administration of interferons at home versus in a physician's office.

Garry Magouirk asked the board to mark their ballots.

Nucleosides and Nucleotides, Combination Agents (AHFS Class 081832)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the only combination agent in this class, interferon alfa-2b plus ribavirin. This is a combination packaged product. Janelle added that much of the adverse event and treatment information from the previous review was also relevant to this review. She explained that oral ribavirin is also available in a single entity formulation and the oral capsules are available in a generic formulation. This combination interferon alfa-2b plus ribavirin product, under the brand name Rebetron, is specifically indicated for chronic hepatitis C in patients with compensated liver disease, previously treated with alfa interferon or who have relapsed following alfa interferon therapy.

The primary toxicity associated with ribavirin is hemolytic anemia. The interferon alfa-2b plus ribavirin combination products does not offer a clinical advantage over the use of single entity interferons plus the addition of ribavirin. Additionally, clinical studies presented with pegylated interferons plus ribavirin have shown a more positive impact on sustained virological response as compared to interferon alfa-2b plus ribavirin. Treatment guidelines also support the use of pegylated interferons plus ribavirin for hepatitis C.

Therefore, as combination interferon therapy is specifically indicated for hepatitis C, due to this narrow indication and limited use, interferon alfa-2b/ribavirin should be available for special needs/circumstances that require medical justification through prior authorization. Medical justification will provide patient access to these agents. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. The recommendation made was no brand combination nucleoside/nucleotide is recommended for preferred status.

Discussion by committee members was initiated by Sheri Boston. Ms. Boston's comment was when it comes to a class like this one, she didn't feel the committee could make a good recommendation without knowing if the agents are being given in the physician's office or by the patient. She asked that this information be included in the review when possible. Louise reminded the committee that PDL decisions should be based on clinical effectiveness of drugs filled at the pharmacy and that what she was hearing two different concerns coming from committee members. One concern is the clinical prior authorization criteria for these agents as it applies to general use, and the other being administration of the drugs/location of the receipt of the drug (self-administration vs. administration in a physician's office). Dr. Feldman asked about prior authorization criteria for these agents. Dr. McIntyre and Louise Jones commented concerning the development/drafting of clinical criteria prior to the P&T meeting, and that these criteria are put in final form only after the recommendations are finalized from the meeting. Dr. McIntyre added that stable therapy is a consideration with the interferons since the labeling of several products states therapy should not be changed from one interferon to another. She described that authorization would include a review of the indications of each interferon and the patient having a diagnosis of one of the labeled indications. Dane Yarbrough asked if a diagnosis of hepatitis C would enable a patient to meet the criteria to obtain one of the interferons and Dr. McIntyre acknowledged it was.

Dr. Holloway questioned whether only the pegylated interferons should be covered for hepatitis C, since the treatment guidelines recommend them. Further clarification was given by Dr. McIntyre that at this time, the pegylated interferons would not be the only interferons covered for hepatitis C. Other interferons have indications for hepatitis C and those would be considered in the prior authorization criteria.

She added that the Agency could consider an educational program to inform prescribers that the clinical evidence strongly supports use of pegylated interferons in the treatment of hepatitis C. Mary McIntyre spoke towards the end of the discussion about trying to keep the discussion within the scope of the responsibilities of the P&T members, and not letting discussion move into other areas such as physician practice.

Dr. Magouirk explained to the board that he felt it was good practice and appropriate to have these drugs under prior authorization, as they are drugs that can result in serious adverse events, and utilization should be monitored very closely. Ben Main commented that his pharmacy doesn't dispense a lot of injectables, but when they have, they haven't had a lot of problems.

Garry Magouirk asked the board to mark their ballots.

Urinary Anti-infectives, Single Entity Agents (AHFS Class 083600)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen described five drug ingredients in the single entity urinary anti-infectives class. At least one generic formulation is available for four of the five drugs in the class. The exception is fosfomycin. Macrobid is a recent generic addition. Although standard therapy for acute uncomplicated bacterial cystitis is trimethoprim/sulfamethoxazole, several agents in the class (nitrofurantoin and fosfomycin) have not shown development of resistance and therefore, continue to have a role in the treatment of urinary tract infections when resistance is an issue. The indications for these drugs are acute uncomplicated urinary tract infections (UTI), with nitrofurantoin, methenamine, and trimethoprim also indicated for prophylaxis of urinary tract infections. Additionally, trimethoprim is indicated for prostatitis.

With regards to efficacy, nitrofurantoin is an effective alternative empiric therapy to trimethoprim/sulfamethoxazole. It's main advantage is in cases where drug allergy, intolerance, or microbial resistance exist. Efficacy and place of therapy for fosfomycin is similar to that previously stated with nitrofurantoin. Methenamine is an alternative to nitrofurantoin, trimethoprim/sulfamethoxazole, and cephalexin in the prevention of recurrent UTI. It has been shown to be slightly less effective, but is well tolerated and shows less incidence of resistance.

Therefore, all single entity brands within the class are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand single entity urinary anti-infective was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the board to mark their ballots.

Urinary Anti-infectives, Combination Agents (AHFS Class 083600)
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen began the discussion in this class, explaining there are five combinations of urinary anti-infectives, with different exact ingredients and brand names. All of the products contain methenamine (40mg to 120mg) with the exception of Uroquid-Acid No. 2 and Urisedamine. Generic alternatives are available for the agents and some OTC combinations are available. The combination urinary anti-infectives are indicated to provide local relief of the symptoms of urinary tract infections, for UTI caused by diagnostic procedures, and for treatment and prevention of cystitis (although generally other first-line antibiotics are used), and these combination agents are simply used to help relieve symptoms, after the infection has been eliminated.

Common drug interactions are with atropine and hyoscyamine, as these drugs can increase GI motility and gastric emptying. Most of the combination agents are well tolerated, with common adverse events mainly due to anticholinergic effects with atropine and hyoscyamine. Additionally, methylene blue can stain bodily fluids, resulting in blue or green urine and/or stool. Limited clinical studies are available for the combination urinary anti-infectives.
Therefore, all brand products within the class are comparable to each other and to the generics and OTC products and offer no significant clinical advantage over other alternatives in general use. No brand urinary anti-infective combination product was recommended for preferred status. Dr. Clark asked if Pyridium was included in this review and Janelle Sheen clarified that not all brands were listed in the review, because there were so many of them. Kelli Littlejohn clarified from the audience that Pyridium is classified under a different AHFS class.

Garry Magouirk asked the board to mark their ballots.

(6) NEW DRUG REVIEWS (Refer to the web for full text reviews): Section II.

Metformin Extended-Release (Fortamet), AHFS Class 682004
Manufacturer comments on behalf of these products:
Fortamet (metformin extended-release)

Janelle sheen presented a brief overview of metformin extended-release. It is indicated for daily use, as monotherapy to diet and exercise, and for concomitant therapy with a sulfonylurea or insulin. Fortamet is available in 500mg and 1000mg tablets. Its absorption is slow and more prolonged compared with immediate-release metformin tablets. This results in a sustained release of extended glycemic control and allows for once-daily dosing. Drug interactions are similar to those with immediate-release metformin. The extent of metformin absorption from metformin extended-release tablets is increased by 60% when given with food. Food decreased the absorption of IR metformin by 40%.

Metformin extended-release QD therapy has demonstrated similar bioavailability to that of BID immediate-release metformin. Adverse events are similar to those reported with IR metformin.

The efficacy of metformin extended-release has been proven clinically non-inferior to BID immediate-release metformin. In the study, this conclusion was based on the mean change in HbA1c from baseline to endpoint of <0.4%. In this same study, 22% of the extended-release patients and 14% of the immediate-release metformin patients discontinued prematurely from the trial. Also, 5% of the patients on metformin extended-release withdrew because of a stated lack of efficacy, as compared with 2% on immediate-release metformin. In a second study, patients on immediate-release metformin were randomized to continue therapy with immediate-release metformin or transition to metformin extended-release. The mean change from baseline in HbA1c values at weeks 12 and 24 were small and similar in the three treatment groups. Patients previously on immediate-release metformin achieved comparable glycemic control when therapy was switched to QD metformin extended-release at the same or greater total daily dose. No direct studies have compared Fortamet with Glucophage XR.

Based on these findings, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand of metformin extended-release (Fortamet) was recommended for preferred status. Dr. Clark asked for clarification on the statement made in reference to hypoglycemia and Janelle Sheen clarified there wasn't a statement specific to hypoglycemia, but rather the study showed comparable glycemic control. Dr. Feldman asked Janelle to clarify what is meant by clinically non-inferior. Janelle explained clinically non-inferior was another way to phrase comparable or similar to. Dr. Feldman also spoke to adherence issues with the extended-release agent and Janelle clarified that a generic metformin extended-release 500mg tablet is available. Discussion further centered around the available products and the clinical evidence, with Dr. Magouirk adding that the difference in HbA1c between the immediate-release and extended-release agents was similar. Dr. Clark brought up the issue of absorption of metformin with food and the big difference between the immediate and extended-release products. It was suggested that this might be something for the DUR board to educate providers on. Janelle commented it is an important education point for dispensing pharmacists as well. Additionally, clinical studies do not suggest that this food interaction difference has an impact on HbA1c. Dr. McIntyre commented that the clinical difference between the immediate-release and extended-release is not significant, even with the difference in food interaction.

Garry Magouirk asked the board to mark their ballots.

Estradiol gel (Estro Gel), AHFS Class 681604
No oral presentations were made by manufacturer representatives on behalf of the drugs in this class.

Janelle Sheen discussed the clinical profile for estradiol gel. She reminded members of the committee that estrogen replacement should be use only for the management of vasomotor symptoms, using the lowest dose for the shortest duration. This estradiol gel has two indications: 1) treatment of moderate to severe vasomotor symptoms associated with menopause, and 2) treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.

Estradiol gel in this product should be applied directly to the skin, from the wrist to the shoulder, and the product dries within 2-5 minutes. Active drug is absorbed by passive diffusion transport across the skin and is formulated to provide a controlled release of active drug. Estradiol gel has similar drug interactions adverse events, and warnings as with other estrogens and has shown minimal skin irritation.

Janelle commented that the product labeling does indicate a 22% mean decrease in average 24-hour serum concentrations of estradiol when the application site is washed one hour after administration.

With dosing, women with a uterus must also receive a progestin to reduce the risk of endometrial cancer. EstroGel comes in a tube or pump. Efficacy studies have shown the gel to be similar in efficacy to oral and transdermal patch formulations of estradiol, in reducing menopausal symptoms. All brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternative in general use. No brand of estradiol gel (EstroGel) was recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee.

Garry Magouirk asked the board to mark their ballots.

Ezetimibe/Simvastatin (Vytorin), AHFS Class 240692
Manufacturer comments on behalf of these products:
Vytorin (ezetimibe/simvastatin)

Janelle Sheen presented a brief overview of clinical information on ezetimibe/simvastatin. The drug works to lower cholesterol in two different ways (production of cholesterol and intestinal absorption of cholesterol). It is indicated for primary hypercholesterolemia and homozygous familial hypercholesterolemia, for HDL inflation in patients with primary or mixed hyperlipidemia, and as an adjunct to other lipid-lowering treatments such as apheresis.

Drug interactions are the same for the combination as with the separate entity drug ingredients. Dosing restrictions do apply with cyclosporine, amiodarone, and verapamil. Dosing is once daily, starting at the 10/20mg dose or the 10/10mg dose if less aggressive LDL reductions are necessary. Efficacy studies have shown ezetimibe/simvastatin reduces LDL levels significantly greater compared with simvastatin monotherapy. The combination effects on HDL wee similar to the effects with simvastatin monotherapy, but were greater than placebo. Additional studies provided similar results with ezetimibe/simvastatin versus simvastatin monotherapy. In one study with atorvastatin compared with ezetimibe/simvastatin, the drug combination group was superior to atorvastatin in decreasing LDL at each dose. Another study showed that adding ezetimibe to simvastatin was more effective than doubling the dose of simvastatin. Finally, no studies have directly compared the efficacy of combination therapy versus coadministration of both agents.

Dose simplification data suggests either administration (the combination vs. coadministration of ezetimibe and simvastatin) provides greater LDL reduction than with statin therapy alone. No studies have directly compared adherence with Vytorin compared with ezetimibe/simvastatin.

Therefore, all brand products within the class reviewed are comparable to each other and to the generics and OTC products in the class and offer no significant clinical advantage over other alternatives in general use. No brand of ezetimibe/simvastatin (Vytorin) is recommended for preferred status. No further discussion on the drugs in this class was made by members of the committee. Garry Magouirk asked the Board to mark their ballots.

(7) RESULTS OF VOTING

Louise Jones announced the results of voting for each of the therapy classes. Results of voting are described in section ten of the minutes.

(8) NEW BUSINESS

No new business was discussed.

(9) CLOSING REMARKS

The next P&T meeting date is to be determined, as the Agency will be working to complete the new ITB and award a new contract for PDL and rebating services.

Louise Jones announced that the future meetings may be slightly different, as it is time to re-review the PDL classes already reviewed, with the possible addition of new therapy classes. This is still to be determined. Louise also asked if the committee preferred to have an all-day meeting or multiple half-day meetings to cover some of the material more efficiently. She commented that it might end up being a combination of both. Louise asked that members let her know, as a show of hands revealed split opinions on the issue.

Louise Jones thanked ACS-Heritage for their superior quality work in completing the pharmacotherapy reviews over the last year. Garry Magouirk adjourned the meeting at 4:16 p.m.

(10) · RESULTS OF THE BALLOTING

A. The P&T Committee voted five (approve as amended) to three (approve as recommended) to accept the amended recommendation that azithromycin (Zithromax) be placed in preferred drug status. Medicaid should place azithromycin (Zithromax) in preferred status on the Preferred Drug List.

Medical Director	☐ Approve	☐ Deny	☐ Approve with modification	☑ Table for future review
Deputy Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☑ Table for future review
Commissioner	☐ Approve	☐ Deny	☐ Approve with modification	☒ Table for future review

B. The P&T Committee voted unanimously to accept the recommendation that no brand combination macrolide antibiotic is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

C. The P&T Committee voted seven (approve as recommended) to one (disapprove) to accept the recommendation that no brand quinolone is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

D. The P&T Committee voted unanimously to accept the recommendation that no brand single entity sulfonamide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

E. The P&T Committee voted unanimously to accept the recommendation that no brand combination sulfonamide is recommended for preferred status. Additionally, the vaginal sulfonamide agents should not be placed in preferred status regardless of cost. Medicaid should accept cost proposals from manufacturers of the oral combination sulfonamides to determine cost effective products and possibly designate one or more preferred agents. Brand vaginal sulfonamides should not be placed in preferred status regardless of cost.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

F. The P&T Committee voted unanimously to accept the recommendation that no brand single entity miscellaneous antibacterial is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

G. The P&T Committee voted unanimously to accept the recommendation that no brand combination miscellaneous antibacterial is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

H. The P&T Committee voted unanimously to accept the recommendation that no brand single entity antimycobacterial is recommended for preferred status. Medicaid should accept cost proposals from the manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

I. The P&T Committee voted unanimously to accept the recommendation that no brand combination antimycobacterial is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

J. The P&T Committee voted unanimously to accept the recommendation that no brand anti-influenza agent is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

K. The P&T Committee voted unanimously to accept the recommendation that no brand interferon is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

L. The P&T Committee voted unanimously to accept the recommendation that no brand combination nucleoside / nucleotide is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

M. The P&T Committee voted seven (approve as recommended) to one (disapprove) to accept the recommendation that no brand single entity urinary anti-infective is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

N. The P&T Committee voted unanimously to accept the recommendation that no brand urinary anti-infective combination product is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

O. The P&T Committee voted unanimously to accept the recommendation that no brand of metformin extended-release (Fortamet) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Deputy Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

Commissioner ☑ Approve ☐ Deny ☐ Approve with modification ☐ Table for future review

P. The P&T Committee voted unanimously to accept the recommendation that no brand of estradiol gel (EstroGel) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

Q. The P&T Committee voted unanimously to accept the recommendation that no brand of simvastatin / ezetimibe (Vytorin) is recommended for preferred status. Medicaid should accept cost proposals from manufacturers to determine cost effective products and possibly designate one or more preferred agents.

Medical Director	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Deputy Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review
Commissioner	☑ Approve	☐ Deny	☐ Approve with modification	☐ Table for future review

Respectfully submitted,

Janelle Sheen — 2-15-2005

Janelle Sheen — Date